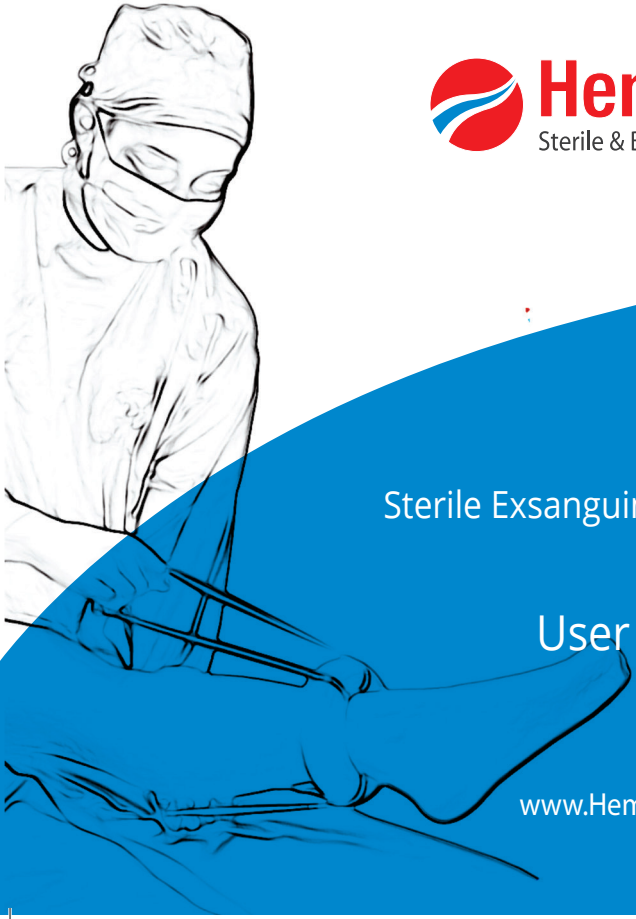

HemaClear®

Sterile & Bloodless Surgical Field

Sterile Exsanguination Tourniquet

User Guide

www.HemaClear.com

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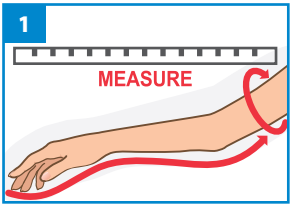
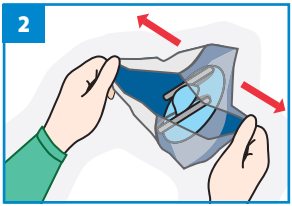
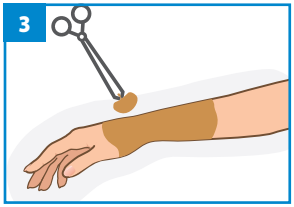
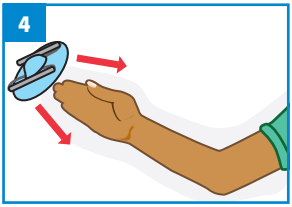
HemaClear® Products including Protective Card and Measuring Tape

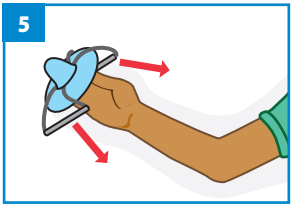
HemaClear® - UPPER EXTREMITY

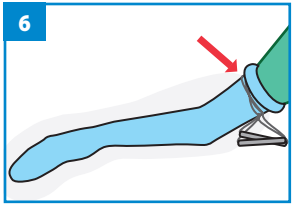


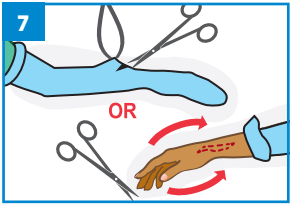


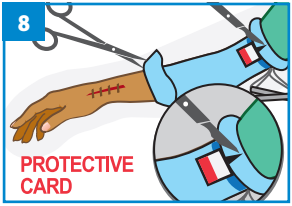




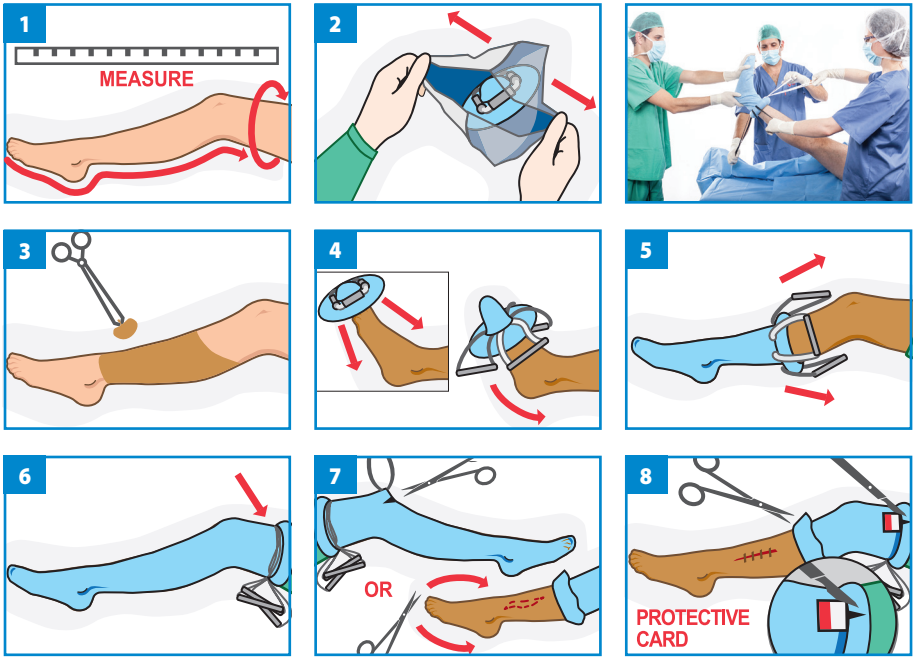




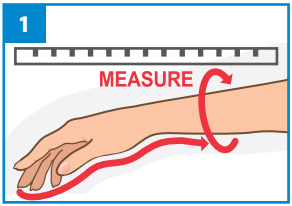


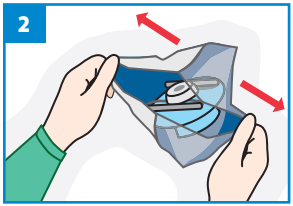


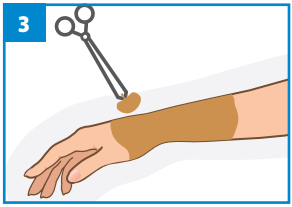
HemaClear® - LOWER EXTREMITY

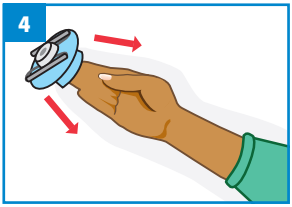


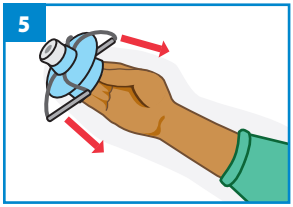
HemaClear® Model F™ for Hand & Wrist Procedures

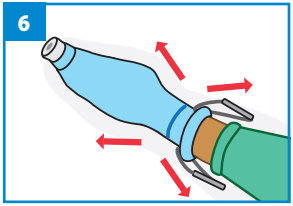


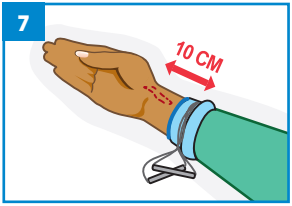


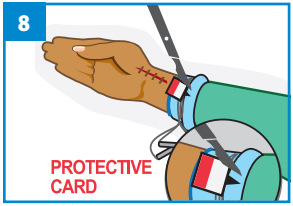




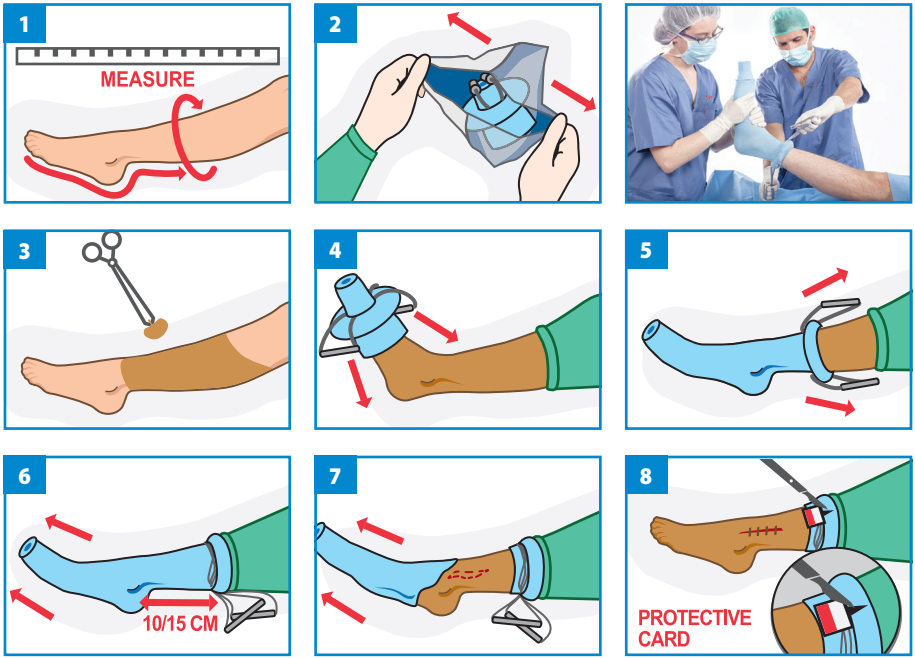








HemaClear® Model A™ for Foot & Ankle Procedures



HemaClear® SELECTION GUIDE

HemaClear® Size	Small	Medium			Large			X-Large
Color	Pink	Green	Red	Yellow	Blue	Orange	Brown	Black & White
Patient's Systolic Blood Pressure Limit	<130 mm Hg	<130 mm Hg	<160 mm Hg	<190 mm Hg	<130 mm Hg	<160 mm Hg	<190 mm Hg	<160 mm Hg
Length	<50 cm	<80 cm			<95 cm	<110 cm		<120 cm
Circumference	14-28 cm	24-40 cm			30-55 cm			50-85 cm

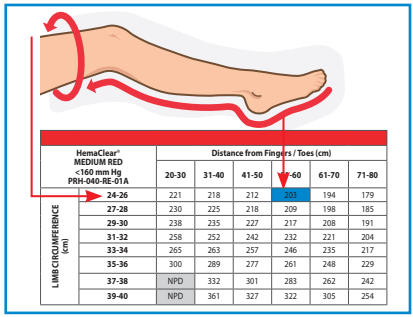
HemaClear® Size	Model F™	Model A™
Color	White	Silver
Systolic Blood Pressure	<160 mm Hg	<160 mm Hg
Distance	<40 cm	<50 cm
Circumference	14-34 cm	22-32 cm

How to Use the HemaClear® Pressure Tables

- Identify the Model to be used (e.g. **HemaClear®** Extra-Large - Black & White).
- Choose the Table section that matches the Model chosen.
- Measure the distance between the tips of the fingers/toes and the occlusion location.
- Find the column corresponding with the distance.
- Measure the limb circumference at the occlusion location.
- Find the row corresponding with the limb circumference.

The intersection of the corresponding column and row presents the pressure exerted by the device to the limb at the skin level of occlusion location.

- Please note that values indicated in the table are within the range of ± 5mm Hg
- NPD: Non-Physiological Dimensions



HemaClear® MEDIUM RED <160 mm Hg PRH-040-RE-01A	Distance from Fingers / Toes (cm)					
LIMB CIRCUMFERENCE (cm)	20-30	31-40	41-50	51-60	61-70	71-80
24-26	221	218	212	205	194	179
27-28	230	225	218	209	198	185
29-30	238	235	227	217	208	191
31-32	258	252	242	232	221	204
33-34	265	263	257	246	235	217
35-36	300	289	277	261	248	229
37-38	NPD	332	301	283	262	242
39-40	NPD	361	327	322	305	254

STORAGE CONDITIONS


Handle with Care


7°-28°C | 45°-83°F


Humidity <60% RH

Latex Free


Single Use

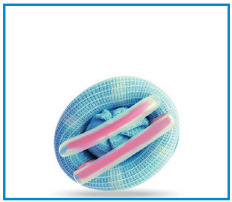
Sterilized by EtO

HemaClear® contains no natural rubber latex.
HemaClear® may be disposed of in accordance with Biological and Medical Waste Disposal procedures.

HemaClear® SMALL PINK

HemaClear® Skin Pressure, mm Hg

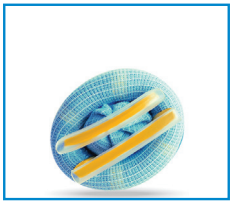
HemaClear® SMALL PINK <130 mm Hg PRH-028-PI-01A		Distance from Fingers / Toes (cm)							
		10-15	16-20	21-25	26-30	31-35	36-40	41-45	46-50
LIMB CIRCUMFERENCE (cm)	14-16	181	173	168	162	157	151	147	142
	17-18	195	189	184	178	173	169	164	160
	19-20	207	202	197	192	188	184	177	174
	21-22	217	212	207	204	198	194	187	183
	23-24	225	220	216	211	207	202	197	193
	25-26	233	229	224	219	217	209	204	201
	27-28	241	235	230	226	221	216	213	209



HemaClear® MEDIUM YELLOW

HemaClear® Skin Pressure, mm Hg

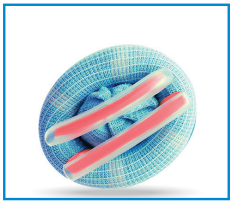
HemaClear® MEDIUM YELLOW <190 mm Hg PRH-040-YE-01A		Distance from Fingers / Toes (cm)					
		20-30	31-40	41-50	51-60	61-70	71-80
LIMB CIRCUMFERENCE (cm)	24-26	231	224	216	208	199	190
	27-28	233	228	222	215	206	196
	29-30	251	242	232	222	214	202
	31-32	270	260	248	236	229	214
	33-34	283	274	265	249	244	226
	35-36	325	304	288	263	259	238
	37-38	NPD	333	314	288	274	249
	39-40	NPD	368	344	339	311	261



HemaClear® MEDIUM RED

HemaClear® Skin Pressure, mm Hg

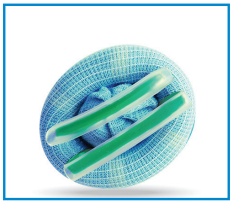
HemaClear® MEDIUM RED <160 mm Hg PRH-040-RE-01A		Distance from Fingers / Toes (cm)					
		20-30	31-40	41-50	51-60	61-70	71-80
LIMB CIRCUMFERENCE (cm)	24-26	221	218	212	203	194	179
	27-28	230	225	218	209	198	185
	29-30	238	235	227	217	208	191
	31-32	258	252	242	232	221	204
	33-34	265	263	257	246	235	217
	35-36	300	289	277	261	248	229
	37-38	NPD	332	301	283	262	242
	39-40	NPD	361	327	322	305	254



HemaClear® MEDIUM GREEN

HemaClear® Skin Pressure, mm Hg

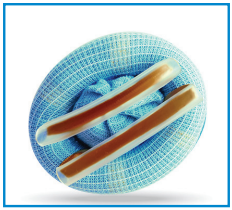
HemaClear® MEDIUM GREEN <130 mm Hg PRH-040-GR-01A		Distance from Fingers / Toes (cm)					
		20-30	**31-40**	**41-50**	**51-60**	**61-70**	**71-80**
LIMB CIRCUMFERENCE (cm)	**24-26**	217	213	203	195	179	162
	27-28	220	217	209	202	187	169
	29-30	232	228	218	210	193	175
	31-32	249	244	233	224	207	188
	33-34	260	253	248	239	221	200
	35-36	287	279	268	253	235	213
	37-38	NPD	324	292	273	238	226
	39-40	NPD	358	318	293	254	239



HemaClear® LARGE BROWN

HemaClear® Skin Pressure, mm Hg

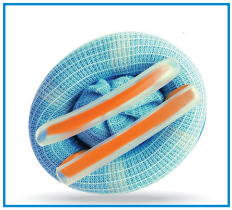
HemaClear® LARGE BROWN <190 mm Hg PRH-060-BR-01A		Distance from Fingers / Toes (cm)						
		40-50	51-60	61-70	71-80	81-90	91-100	101-110
LIMB CIRCUMFERENCE (cm)	30-32	310	301	296	281	276	264	257
	33-36	362	355	346	337	332	320	311
	37-40	387	379	370	363	354	344	337
	41-44	NPD	429	407	389	376	367	363
	45-48	NPD	NPD	436	412	395	389	384
	49-52	NPD	NPD	NPD	425	409	406	400
	53-55	NPD	NPD	NPD	432	422	418	413



HemaClear® LARGE ORANGE

HemaClear® Skin Pressure, mm Hg

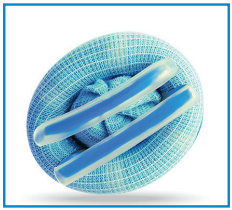
HemaClear® LARGE ORANGE <160 mm Hg PRH-060-OR-01A		Distance from Fingers / Toes (cm)						
		40-50	51-60	61-70	71-80	81-90	91-100	101-110
LIMB CIRCUMFERENCE (cm)	30-32	281	276	264	257	250	236	229
	33-36	341	332	320	311	306	285	281
	37-40	365	355	344	337	326	307	302
	41-44	NPD	423	390	363	346	328	324
	45-48	NPD	NPD	413	372	352	335	324
	49-52	NPD	NPD	NPD	387	357	341	324
	53-55	NPD	NPD	NPD	415	365	349	346



HemaClear® LARGE BLUE

HemaClear® Skin Pressure, mm Hg

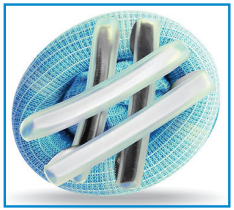
HemaClear® LARGE BLUE <130 mm Hg PRH-060-BL-01A		Distance from Fingers / Toes (cm)					
		40-50	51-60	61-70	71-80	81-90	91-95
LIMB CIRCUMFERENCE (cm)	30-32	264	257	250	236	229	216
	33-36	326	311	306	285	281	261
	37-40	363	342	326	307	302	293
	41-44	NPD	371	348	328	324	324
	45-48	NPD	NPD	357	335	324	326
	49-52	NPD	NPD	NPD	341	329	328
	53-55	NPD	NPD	NPD	347	341	335



HemaClear® EXTRA-LARGE BLACK & WHITE

HemaClear® Skin Pressure, mm Hg

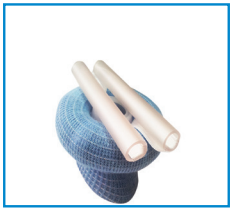
HemaClear® EXTRA LARGE BLACK & WHITE <160 mm Hg PRH-090-BW-01A		Distance from Toes (cm)					
		60-70	71-80	81-90	91-100	101-110	111-120
LIMB CIRCUMFERENCE (cm)	50-54	300	296	292	289	285	281
	55-60	315	311	307	304	300	296
	61-66	327	323	320	316	313	310
	67-72	337	333	330	326	323	320
	73-78	345	342	338	335	331	328
	79-85	352	349	346	342	339	336



HemaClear® Model F™

HemaClear® Skin Pressure, mm Hg

HemaClear® MODEL F™ (Forearm) <160 mm Hg PRH-035-FA-01A		Distance from Fingers (cm)		
		25-30	31-35	36-40
LIMB CIRCUMFERENCE (cm)	14-18	204	197	192
	19-22	236	231	227
	23-26	257	254	247
	27-30	276	270	264
	31-34	295	286	281



HemaClear® Model A™

HemaClear® Skin Pressure, mm Hg

HemaClear® MODEL A™ (Foot & Ankle) <160 mm Hg PRH-032-MA-01A		Distance from Toes (cm)				
		30-34	**35-38**	**39-42**	**43-46**	**47-50**
LIMB CIRCUMFERENCE (cm)	**22-24**	176	167	161	NPD	NPD
	25-26	184	177	170	164	NPD
	27-28	191	184	177	170	165
	29-30	NPD	190	183	177	171
	31-32	NPD	NPD	188	182	176

PLEASE READ THIS PACKAGE INSERT CAREFULLY
in Its Entirety Before Using the Device

HemaClear® Instructions for Use

Indications for Use

HemaClear® is indicated for expelling blood from a limb, occluding arterial flow into a limb, and placing a sterile stockinet over a limb.

Contraindications

- Do not use **HemaClear®** on patients with poor peripheral blood flow, edema, or Deep Vein Thrombosis (DVT). See the Wells Score System (next page), for likelihood of DVT.
- Do not use **HemaClear®** if the limb is infected or with malignancy.
- Do not apply **HemaClear®** directly on skin that is fragile or has significant lesions. Use a sterile ace bandage to protect fragile skin before applying **HemaClear®**.
- **Do not leave HemaClear® on a patient's limb for more than 120 minutes.**
- Do not place **HemaClear®** directly over the ulnar nerve (at the elbow) or the peroneal nerve (at the proximal tibia).

DVT Probability: Wells Score System[1]

CLINICAL FEATURE	POINTS	PATIENT SCORE
Active cancer (treatment ongoing, within 6 months, or pallative)	1	
Paralysis, paresis or recent plaster immobilization of the lower extremities	1	
Recently bedridden for 3 days or more or major surgery within 12 weeks requiring general or regional anesthesia	1	
Localized tenderness along the distribution of the deep venous system	1	
Entire leg swollen	1	
Calf swelling at least 3 cm larger than asymptomatic side	1	
Pitting edema confined to the symptomatic leg	1	
Collateral superficial veins (non-varicose)	1	
Previously documented DVT	1	
An alternative diagnosis is at least as likely as DVT	-2	
Clinical probability simplified score		
DVT *likely*	2 or more	
DVT *unlikely*	1 or less	

[1] Wells PS, Anderson DR, Rodger M et al. (2003). Evaluation of D-dimer in the diagnosis of a suspected deep-vein thrombosis. New England Journal of Medicine 349: 1227–35.

⚠ Warnings

- **HemaClear®** should be operated by a physician, or by the order of a physician.
- If the limb is unstable (fracture, dislocation), apply axial traction to stabilize the limb during **HemaClear®** application.
- **HemaClear®** only occludes arterial blood flow as long as the patient's systolic blood pressure does not exceed the recommended limit. Please refer to the **Selection Guide** for the specific limit of a patient's systolic blood pressure for each Model.
- **HemaClear®** devices can be applied to limbs with a circumference (at the occlusion location) ranging between 14 cm and 85 cm.
  Do not use HemaClear® if the circumference at the occlusion location is smaller than 14 cm or greater than 85 cm. Please refer to the **Selection Guide** for specific circumference range of each Model.
- If **HemaClear®** does not stop the blood flow to a limb, it should be removed immediately.

⚠ Side Effects

1. **Temporary discoloration of the skin beneath the HemaClear® Ring** (<24 hours).
2. **Residual pain at the occlusion location** - may last up to 7 days (rare).
3. **Tourniquet Failure**
   - **Primary Tourniquet Failure** - Incomplete occlusion of arterial flow from the beginning of the case.
   - **Secondary Tourniquet Failure** - Occlusion breach following initial successful occlusion.

   Both failures are uncommon and usually result from the patient's systolic blood pressure exceeding the recommended limit for the specific **HemaClear®** Model.

Directions for Use

1. Measure the limb circumference at the occlusion location using the **Measuring Tape** provided, which is color coded according to circumference, in order to select the correct **HemaClear®** Model (Small, Medium, Large, Extra-Large). Verify that the circumference corresponds to the device range according to the **Selection Guide**.
   - For upper extremity procedures, the occlusion location should be 10 cm above the wrist for hand procedures, or mid upper arm (or higher) for forearm, elbow, and distal humerus procedures.
   - For lower extremity procedures, the occlusion location should be 5-15 cm above the lateral mallelous (below the calf muscles) for foot procedures, or mid or upper thigh for ankle, lower leg, knee, or distal femur procedures.
2. Measure the distance from the tips of the fingers/toes to the occlusion location. Verify that the distance does not exceed the device maximal length according to the **Selection Guide**.
3. Verify that the patient's systolic blood pressure does not exceed the limit specified in the **Selection Guide** for the selected **HemaClear®** Model.
4. Refer to the appropriate color coded **Pressure Table** for device pressure at skin level.
5. Using a sterile technique, open the outer envelope of the device and drop it onto the sterile field, with inner envelope intact. Use a sterile technique to remove the

device from within the inner envelope. Keep the **Protective Card** for the end of the procedure to protect the skin when the silicone ring is cut, in keeping with instructions regarding use of the Protective Card.

6. If the patient is awake, explain the application procedure and warn about possible ring pressure discomfort. Sedation and/or analgesia may be used. Disinfect the limb according to the type of procedure performed. Apply sterile drapes so that they overlap the edge of the disinfected region.

   UPPER EXTREMITY: Insert fingertips into the orifice of the device with the handles facing away from the patient (Pg. 4, Fig. 4). Ensure that all fingers are inserted into the circumference of the ring (Pg. 4, Fig. 5). Have an assistant stabilize the hand by holding it from the palm side (Pg. 4, Image top left). Firmly grab the two plastic handles using the colored straps, and pull the handles proximally along the arm to the desired occlusion location (Pg. 4, Fig. 5).

   LOWER EXTREMITY: Insert the toes into the orifice of the device with the handles facing away from the patient. Ensure that all the toes are inserted into the circumference of the ring. Position the device on the toes so that one handle is aligned with the bottom (sole) of the foot, and the other handle is aligned with the top of the foot (Pg. 5, Fig. 4). Stand proximally to the patient's foot, so that when pulling the device straps proximally on the patient's leg, you are pulling towards your body. Have an assistant stabilize the foot and ankle fo the patient (Pg. 5, Image

top right). Firmly grab the two plastic handles using the colored straps, and pull the handles first along the foot and then proximally along the leg. To roll **HemaClear®** over the heel, apply more force to the bottom handle, using it as a hinge. Once over the heel, continue pulling on the handles until **HemaClear®** reaches the desired occlusion location (Pg. 5, Fig. 5).

Occlusion locations: A) On the calf (5-15 cm above the medial mallelous, below the calf muscle) or B) On the thigh (at or above the mid-thigh).

NOTE: **HemaClear®** should be placed within the sterile field on the limb over the edge of the sterile drapes.

7. Once **HemaClear®** is in place, the colored straps can either be wrapped around the limb, distal to the **HemaClear®** ring, or cut off (Pg. 5, Fig. 6).
8. Expose the incision site by pulling the stockinet up, removing it, or cutting a window in the fabric (Pg. 5, Fig. 7).

   NOTE: To minimize lint, dampen the fabric with sterile water or saline before cutting it.
9. **Tourniquet Time** begins as soon as the **HemaClear®** is in place. Tourniquet Time ends when the **HemaClear®** is removed (Pg. 5, Fig. 8).
10. When the procedure is over, insert the **Protective Card** under the ring from its distal side by pulling one of the straps and cut the ring with a scalpel. Use scissors to cut and remove the remaining stockinet. Blood flow to the limb will resume.

HemaClear® Model F™ for Hand & Wrist Procedures

For **HemaClear® Model F™** please follow the general Directions for Use as specified above, including the following:

1. If the circumference of the forearm at the desired occlusion location is less than 14 cm, use a stockinet to build up the forearm circumference to 14-16 cm. If the circumference at the desired occlusion location is not within the 14-34 cm range, use another appropriate **HemaClear®** Model.
2. Insert the finger tips into the oval opening of the device application cup with the handles facing away from the patient. Verify that all fingers are inserted. Grab the handles firmly and pull them proximally towards the patient, along the forearm. The device will roll smoothly up the hand and the forearm.
3. The recommended placement location on the forearm is 10 cm (4") proximal to the wrist.
4. The **HemaClear® Model-F™** is constructed with two segments of elastic stockinet. Once the device reaches the occlusion location, the distal sleeve (covering the fingers) can be easily pulled away and removed, or cut to reveal the surgical site. If it is decided to cut the stockinet, apply sterile water or saline, before cutting the stockinet. The surgical site may be covered with a sterile transparent drape if desired.
   NOTE: Wetting the stockinet prior to cutting minimizes the amount of free fabric fragments.

HemaClear® Model A™ for Foot & Ankle Procedures

For **HemaClear® Model A™** please follow the general Directions for Use as specified above, including the following:

1. The recommended placement location on the lower leg is from 5-15 cm (2-6") above the lateral malleolus.
2. If the circumference at the desired occlusion location is not within 22-32 cm, use another appropriate **HemaClear®** Model.
3. If the patient's foot is larger than 29 cm (shoe size 14 or larger USA, or 47 or larger in Europe) use **HemaClear®** Large (Orange or Brown) at the same lower leg location specified for **Model A™**.
4. Insert the tips of the toes into the oval opening of the device application cup with the handles facing away from the patient. Verify that all toes are inserted. Grab the handles firmly and pull them proximally towards the patient, along the axis of the foot. Use the bottom handle to pull **HemaClear®** over the heel. Roll the device on the lower leg until it reaches the desired occlusion location.
5. The device will not roll beyond 50 cm (20") from the tips of the toes. If a more proximal position is required, use an alternative **HemaClear®** Model (**HemaClear®** Large or **HemaClear®** Extra-Large).
6. The **HemaClear® Model-A™** is constructed with two segments of elastic stockinet.

Once the device reaches the desired occlusion location, the distal sleeve (covering the applicator and toes) can be easily pulled away and removed, or cut to reveal the surgical site. If it is decided to cut the stockinet, apply sterile water or saline before cutting the stockinet. The surgical site may be covered with a sterile transparent drape if desired.

NOTE: Wetting the stockinet prior to cutting minimizes the amount of free fabric fragments.

WARRANTY

Subject to the herein restrictions and limitations, Oneg Hakarmel Ltd. (OHK Medical Devices, Inc.) (the "Manufacturer") hereby warrants to the original purchaser of the HemaClear® product(s) (the "Product"), that the Product shall be free from defects in material and workmanship for the period specified within the Expiration Date printed on the Product packaging, in accordance with the record of the Manufacturer, which shall constitute a prima-facie evidence in that respect. Otherwise the Product is provided AS-IS.

SCOPE OF WARRANTY

This warranty is expressly conditioned on the purchaser's obligation to use and store the Product in accordance with applicable law and the required instructions specified by the Manufacturer, including without limitations with respect to the maintenance and/or use of the Product, (and specifically, using the appropriate size of the Product per each patient, adhering to instructions regarding the Product's shelf life and actual use time on any patient, verifying that the Product shall not expose the respective patient to any health risk per such patient's medical condition, etc.). The above is also subject to the Product being stored and handled per the above, by any distributor or other party which supplied the Product to the purchaser.

The purchaser understands that Manufacturer's instructions may also be updated and published at Manufacturer's website (www.hemaclear.com), and it is the purchaser's responsibility to monitor any such changes.

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Warranty

Subject to the herein restrictions and limitations, OHK hereby warrants You that the Device shall be free from defects in material and workmanship for a period of two (2) years from the manufacturing date of the Device, in accordance with the record of OHK, which shall constitute a prima-facie evidence in that respect.

Scope of Warranty

This warranty is expressly conditioned on Your obligation to use and store the Device in accordance with applicable law and the required instructions specified by OHK, including without limitations with respect to the maintenance and/or use of the Device (and specifically, without derogating from the generality of the foregoing, using the appropriate size of the Product per each patient, adhering to instructions regarding the Device's shelf life and actual use time on any patient, verifying that the Device shall not expose the respective patient to any health risk per such patient's medical condition, etc.). The above is also subject to the Device being stored and handled per the above, by any distributor or other party which supplied the Device to You. You understand that OHK's instructions may also be updated and published at OHK's website, and it is Your responsibility to monitor any such changes.

You acknowledge receiving such instructions, and without derogating from the provisions herein, You agree to be bound by such instructions. If You do not comply with the applicable instructions, then all warranty granted by OHK shall be void, and the You shall bear the full costs of (a) replacing the Device (including, but not limited to all shipping costs), and (b) any claims brought against it and/or any of its employees, agents, directors, affiliates, etc. relating to its use of the Device, and shall be further required to indemnify OHK for any such claims.

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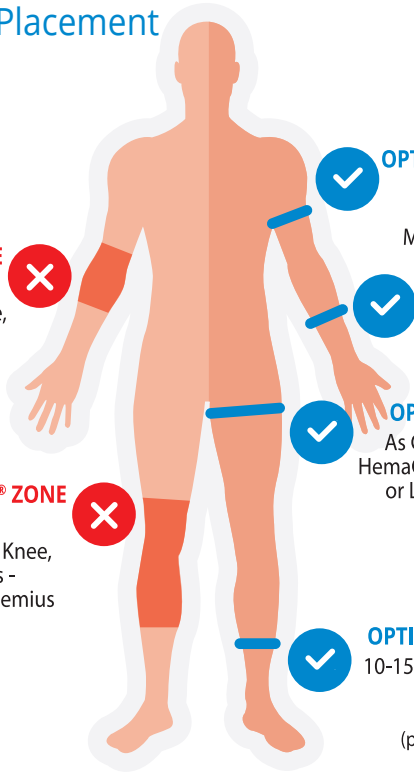
HemaClear® Placement



NO-HEMACLEAR® ZONE ARM
Ulnar Nerve, Radial Nerve, Elbow, Forearm Muscles

NO-HEMACLEAR® ZONE LEG
Peroneal Nerve, Knee, Calf Muscles - Soleus/Gastrocnemius

OPTIMAL POSITION - UPPER ARM
Bottom of Deltoid Muscle
HemaClear®
Medium Yellow or Large Orange

OPTIMAL POSITION - FOREARM
10 cm Above the Wrist
Distal to Forearm Muscles
HemaClear® Model F™

OPTIMAL POSITION - THIGH
As Close to the Groin as Possible
HemaClear® Extra-Large Black & White
or Large Orange or Large Brown

OPTIMAL POSITION - LOWER LEG
10-15 cm Above the Lateral Malleolus
HemaClear® Model A™
or Large Orange
(patient shoe size ≥ US14 / EU27)

HemaClear®

Sterile & Bloodless Surgical Field

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